UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DAVID HACKEL, *individually and on behalf of all others similarly situated,*	*	
Plaintiff,	*	
v.	*	Civil Action No. 19-cv-10783-ADB
AVEO PHARMACEUTICALS, INC. et al.,	*	
Defendants.	*	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

BURROUGHS, D.J.

This is a federal securities class action lawsuit concerning alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j, 78t, and Rule 10b-5, 17 C.F.R § 240.10b-5, by Defendant AVEO Pharmaceuticals ("AVEO" or "the Company") and certain of its current and former executives, including Michael Bailey, Matthew Dallas, Keith S. Ehrlich, and Michael Needle (together with AVEO, "Defendants"). [ECF No. 39 ("Am. Compl.")]. Lead Plaintiff Andrej Hornak ("Plaintiff"), individually and on behalf of a putative class, claims that Defendants made false and misleading statements between May 4, 2017 and November 5, 2019 (the "Class Period"), in connection with its efforts to demonstrate the effectiveness of a candidate drug for treating renal cell carcinoma. See [Am. Compl.]. Currently before the Court is Defendants' motion to dismiss. [ECF No. 51]. For the reasons stated herein, Defendants' motion, [ECF No. 51], is GRANTED.

I. BACKGROUND

A. Factual Background

For purposes of this motion, the relevant facts are drawn from Plaintiff's amended complaint, [Am. Compl.], and viewed in the light most favorable to Plaintiff. Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014). In addition to Plaintiff's amended complaint, the Court "may consider 'documents the authenticity of which are not disputed by the parties; . . . documents central to plaintiffs' claim; [and] documents sufficiently referred to in the complaint.'" Curran v. Cousins, 509 F.3d 36, 44 (1st Cir. 2007) (alteration in original) (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)). These include AVEO's filings with the Securities and Exchange Commission ("SEC") and press releases, which Plaintiff relies on extensively in his amended complaint. See [Am. Compl.].

AVEO is a biopharmaceutical company that, during the Class Period, was developing a once-daily oral medication for the treatment of renal cell carcinoma ("RCC"). [Am. Compl. ¶ 2]. The Company's lead drug candidate is tivozanib, which is approved for use in the European Union but is still undergoing clinical trials in the United States in an effort to obtain approval from the Food & Drug Administration ("FDA"). [Id. ¶¶ 2, 134; ECF No. 52 at 6 (stating that "AVEO is in the process of seeking approval" for tivozanib from the FDA)]. Defendant Bailey has referred to tivozanib as "the central focus" of the Company's strategy, though it also has other drugs in development. [Am. Compl. ¶¶ 53, 56].

Once a pharmaceutical company has gathered "substantial evidence" of a drug's efficacy and safety, it may submit a New Drug Application ("NDA") to FDA. [Am. Compl. ¶¶ 34–37]. This "substantial evidence" is obtained through three phases of clinical trials, culminating in Phase 3 clinical trials involving human subjects. [Id. ¶¶ 36–37]. Clinical trials for cancer

treatments typically measure two outcomes: overall survival ("OS"), which measures how long a patient lives after treatment, and progression-free survival ("PFS"), which measures how long a patient lives and for how long the disease stops progressing after treatment. [Id. ¶ 43]. OS is measured by patient death, while PFS is measured by imaging tumor size and patient death. [Id. ¶ 43]. Measuring OS takes longer than PFS because, even if a patient has completed treatment, OS cannot be measured until a patient dies. [Id. ¶ 45]. Data on OS and PFS may become impossible to obtain if a subject is "lost to follow-up," which can mean that they have stopped participating in the trial, have become unreachable, or their data has been lost due to mechanical error. [Id. ¶ 112]. If data on a "lost to follow-up" subject is later identified, that recovered data can potentially change the clinical study results. See [id. ¶¶ 117–18]. OS or PFS can be used as the primary endpoint in a clinical trial for a drug that treats RCC, though the FDA has "routinely considered" OS even when PFS is selected as the primary endpoint for a study. [Id. ¶ 48].

On May 26, 2016, AVEO announced the start of a new Phase 3 clinical trial, TIVO-3, which was designed as a "randomized, controlled, multi-center, open-label study" that would compare AVEO's tivozanib to a competitor's drug, sorafenib. [Am. Compl. ¶ 10]. TIVO-3 was intended to address FDA concerns about the OS of patients from a previous study, TIVO-1. [Id. ¶ 10]. The study was initially designed to enroll 351 subjects who would either be administered tivozanib or sorafenib, though that number later dropped to 322. [Id. ¶¶ 58, 62–63]. The Company announced that the primary endpoint for the study was PFS, with OS as one of several secondary endpoints. [Id. ¶ 62]. The Company also announced that a "topline readout" of study results was "projected" to be available in the first quarter of 2018. [Id.]. Due to a slowdown in PFS events throughout 2018, however, topline analysis was not conducted until the fourth

quarter of 2018. [Id. ¶¶ 90, 99].[1] As early as June 2017, the Company reported its plan to conduct topline analysis of 255 events, but in October 2018 the Company announced that it would analyze only 242 events due to the slow pace of events and the fact that the reduction in events would not significantly alter their interpretation of the results. [Id. ¶ 74 (stating that the Company planned to analyze 255 events, which would provide 90% power to the analysis); id. ¶ 88 (stating that the Company would analyze 242 events, decreasing the power of the study from 90% to 88%)].

By November 5, 2018, AVEO disclosed the topline results of the TIVO-3 study, noting that tivozanib had "met its primary endpoint of demonstrating a statistically significant benefit in progression-free survival . . . ." [Am. Compl. ¶ 99]. At the same time, AVEO reported initial OS results, but noted that OS data would not be mature until nearly a year later. [Id. ¶ 209]. The Company announced that its goal was to submit an NDA "in approximately six months," [id. ¶ 100], and quoted Defendant Bailey as saying that the results were "[the] first step in our goal to improve both outcomes and patient experience," [id. ¶ 101].

Plaintiff identifies two categories of Defendants' statements as being materially false and misleading: 1) statements about the timing by which topline data would be available for analysis, and 2) statements made on November 5, 2018 about OS data. [ECF No. 56 at 14 n.3 (waiving claims based on any other alleged misstatements raised in the amended complaint)].

1. Alleged Misrepresentations During the Class Period

a. Statements About the Timing of Topline Data

The alleged misstatements were made in quarterly and annual filings submitted to the SEC, as well as in press releases. The first alleged misstatement was made in May 2017 in a

[1] Defendants explain that "topline results" refer to primary endpoint analysis and relevant safety data. [ECF No. 52 at 9 n.3].

quarterly report ("10-Q") for the first quarter of 2017, when AVEO reported, "[w]e expect . . . to report top line data in the first quarter of 2018." [ECF No. 53-16 at 31; Am. Compl. ¶ 136]. Press releases issued in May, June, August, October, and November 2017 also stated that "topline data" for the trial was "expected" or "anticipated" in the first quarter of 2018. [ECF No. 53-3 at 3; ECF No. 53-4 at 2; ECF No. 53-5 at 2; ECF No. 53-6 at 2; ECF No. 53-7 at 2; Am. Compl. ¶¶ 140–41, 143, 149, 151, 158].[2]

In a February 12, 2018 press release, AVEO adjusted the expected timing of the release of its topline data to the second quarter of 2018, describing this as a "potential" milestone for 2018. [ECF No. 53-10 at 2; Am. Compl. ¶ 164]. Press releases from March 2018 reflected this new "expected" timeline for reporting topline results from the study. [ECF No. 53-11 at 3 ("Based on the current rate of progression-free survival (PFS) events, the Company expects the TIVO-3 trial to read out in the second quarter of 2018."); ECF No. 53-12 at 2 ("[W]e expect top-line results from this study to read out in the second quarter of this year."); Am. Comp. ¶¶ 173, 175]. In its annual report for 2017 ("10-K"), filed with the SEC in March 2018, AVEO also stated that it "expect[ed] to receive and report topline data from the TIVO-3 trial . . . in the second quarter of 2018." [ECF No. 53-19 at 7; Am. Compl. ¶ 168].

The Company again adjusted its expected timeline in its 10-Q filing for the first quarter of 2018, filed in May of that year, now estimating that topline results would be ready in the third quarter of 2018. [ECF No. 53-20 at 38; Am. Compl. ¶ 180]. This was also reflected in a press release issued in connection with the 10-Q filing, in which AVEO stated that topline results were

[2] Press releases from December 7, 2017 and January 2, 2018 stated generally that topline results from TIVO-3 were "anticipated" in 2018, [Am. Compl. ¶ 160; ECF No. 53-8 at 2], or that the Company "continue[d] to look forward to . . . the receipt of topline results from the TIVO-3 trial," [Am. Compl. ¶ 162; ECF No. 53-9 at 2].

expected in the third quarter of 2018 because "the pre-specified number of progression free survival (PFS) events required to trigger data analysis of the Phase 3 TIVO-3 trial have not been reached at this time." [ECF No. 53-13 at 2; Am. Compl. ¶ 185].

By June 2018, in the Company's 10-Q for the second quarter of 2018, the Company further adjusted that timeline to state that it anticipated reporting topline results in the fourth quarter of 2018, once 255 PFS events had occurred. [ECF No. 53-21 at 38; Am. Compl. ¶ 191]. This new timing was echoed in a July 2018 press release, which stated that results were now expected in the fourth quarter of 2018 due to "PFS events occurring slower than forecasted, combined with ten patients being removed or 'censored' from the PFS event count" due to an "administrative error." [ECF No. 53-14 at 2; Am. Compl. ¶ 188]. The press release further stated that it was AVEO's intention to wait to analyze and report results until "after the trial records 255 progression free survival (PFS) events." [ECF No. 53-14 at 2; Am. Compl. ¶ 188]. This anticipated timeline was repeated in an August 2018 press release. [ECF No. 53-15 at 2; Am. Compl. ¶ 198].

In addition to SEC filings and press releases, Plaintiff also cites to statements that Defendant Bailey made at an April 2018 conference, during which he said that the Company was "targeting to get top line data . . . [in] the second quarter of 2018." [ECF No. 53-2 at 2; Am. Compl. ¶ 178].

As to the statements described above, Plaintiff claims that Defendants knew or recklessly disregarded that the statements were materially misleading because they knew that PFS events were not taking place quickly enough to meet the Company's public estimate for reporting topline results from TIVO-3. See [Am. Compl. ¶¶ 139, 142, 144, 148, 150, 153, 157, 159, 161, 163, 165, 172, 174, 176, 179, 183, 187, 190, 196, 199].

b. Statements Made on November 5, 2018

On November 5, 2018, AVEO issued a press release with the results of its analysis of the topline results from TIVO-3. [Am. Compl. ¶ 208]. The Company stated that "[t]he trial met its primary endpoint of demonstrating a statistically significant benefit" in PFS. [ECF No. 53-23 at 2]. While noting that "analysis of the secondary endpoint of overall survival (OS) was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported," the Company shared that "preliminary OS analysis" showed "no statistically significant difference in OS" between tivozanib and sorafenib. [Id.]. The final analysis of OS results was "planned for August 2019, two years following the last patient enrolled." [Id.]. Lastly, the Company announced its "goal" of submitting an NDA for tivozanib "in approximately six months." [Id. at 3]. Plaintiff notes that the press release did not mention that some subjects had been lost to follow-up. [Am. Comp. ¶ 212].

That same day, AVEO held an investor call to discuss the results reported in its press release. [Am. Compl. ¶ 215]. Defendant Needle made the following statement regarding the preliminary OS results reported by the Company:

> A few things to consider regarding the preliminary OS outcome. First, overall survival was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported, representing 161 patients. 149 patients remained in active follow-up, another 41 patients withdrew consent or were lost to follow-up. Of those that withdrew consent, twice as many were randomized to the sorafenib arm. Efforts are underway to determine the survival status of as many of these patients as possible. . . . [A] little over 40 patients remain on study therapy . . . . [therefore t]hese patients will continue to affect the OS analysis. . . . [W]e cannot currently make any predictions about what the final OS analysis for TIVO-3 will show . . . .

[ECF No. 53-1 at 6–7]; see [Am. Compl. ¶ 216].

With regard to the statements described above, Plaintiff claims that AVEO and Defendants Bailey and Needle knew or recklessly disregarded that the statements were

materially misleading because the OS results a) were insufficient to obtain FDA approval; b) did not include all OS events; and c) would risk delayed FDA approval for tivozanib. See [Am. Compl. ¶¶ 214, 219].

2. Allegations of Scienter

Throughout the TIVO-3 trial, AVEO needed to boost its operating capital through private placement of stock, public offerings, and loans. [Am. Compl. ¶¶ 60, 71, 87, 200]. In earnings reports released during the Class Period, the Company acknowledged that its survival was "substantially dependent on the success of tivozanib," [id. ¶ 2], and success of the trial was repeatedly emphasized as critical to the Company's future, [id. ¶¶ 59, 64]. At a February 14, 2018 conference, Defendant Bailey told attendees that, "we got [sic] to hit it out of the park here, or I think we're going to be [sic] an uphill battle with regard to tivozanib." [Id. ¶¶ 79, 167]. At an April 10, 2018 conference, Defendant Bailey delivered a similar message when he said, "we can't afford for this study to fail." [Id. ¶¶ 82, 177].

3. Allegations of Loss

Plaintiff claims that AVEO stock dropped by 10% on October 1, 2018, in response to a press release announcing that only 242 PFS events would be analyzed rather than 255 events as previously planned. [Am. Compl. ¶¶ 95, 204, 207].[3]

On January 31, 2019, AVEO announced that it had accepted the FDA's recommendation to delay filing an NDA, explaining that the Company planned to wait for "more mature OS results" before submitting an NDA for tivozanib. [Id. ¶ 115]. That same day, the Company's

[3] Although not included in his amended complaint, in his opposition Plaintiff states that AVEO stock dropped 20% in response to the Company's November 5, 2018 release of topline data. [ECF No. 56 at 14].

stock dropped from $1.07 per share to a closing price of $0.70 per share. [Id. ¶ 122]. The following day, analysts downgraded the stock. [Id. ¶ 131].

B. Procedural Background

On February 25, 2019, David Hackel filed a complaint against Defendants in the Southern District of New York. [ECF No. 1]. The case was later transferred to this district. [ECF No. 14]. On May 6, 2019, the Court appointed Plaintiff as Lead Plaintiff and approved his selection of Pomerantz LLP as Lead Counsel and Andrews DeValerio LLP as Liaison Counsel. [ECF No. 35]. On July 24, 2019, Plaintiff filed his amended complaint, [Am. Compl.], which Defendants moved to dismiss on September 27, 2019, [ECF No. 51]. Plaintiff opposed, [ECF No. 56], and Defendants replied, [ECF No. 57].

II. LEGAL STANDARD

"Section 10(b) of the Securities Exchange Act of 1934 forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (alterations in original) (quoting 15 U.S.C. § 78j(b)). In turn, SEC Rule 10b-5 implements § 10(b) by declaring it unlawful, "in connection with the purchase or sale of any security,"

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b-5. Therefore,

> [t]o survive a motion to dismiss under Rule 12(b)(6), a complaint alleging securities fraud under section 10(b) of the Exchange Act and Securities and Exchange Commission Rule 10b-5 must plead six elements: '(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation.'

Kader v. Sarepta Therapeutics, Inc., 887 F.3d 48, 56 (1st Cir. 2018) (quoting ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)).[4]

As with any motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must "accept as true all well-pleaded facts alleged in the complaint and draw all reasonable inferences therefrom in the pleader's favor." A.G. ex rel. Maddox v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013) (quoting Santiago v. P.R., 655 F.3d 61, 72 (1st Cir. 2011)). To survive a motion to dismiss, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

Further, because this case involves claims of securities fraud, Plaintiff must additionally satisfy the Federal Rule of Civil Procedure 9(b) standard for alleging fraud with particularity and comply with the heightened pleading requirements imposed by the Private Securities Litigation Reform Act ("PSLRA"). See Advest, Inc., 512 F.3d at 58. The PSLRA "requires plaintiffs'

[4] "Claims brought under section 20(a) of the [Securities Exchange] Act, 15 U.S.C. § 78t(a), are derivative of 10b-5 claims." Hill v. Gozani, 638 F.3d 40, 53 (1st Cir. 2011). Section 20(a) provides that once a company has been found to have violated the Act's substantive provisions, "[e]very person who, directly or indirectly, controls" the company "shall also be liable jointly and severally with and to the same extent as [the company] . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a). Here, Plaintiff alleges a Section 20(a) claim against Defendant Bailey on the grounds that he "controlled the operation and management of AVEO, and directed and oversaw AVEO's business and regulatory affairs and investor communications," and therefore "knew the material adverse non-public information omitted from investors" as alleged in the amended complaint. See [Am. Compl. ¶ 251]. Accordingly, in order to plead a viable Section 20(a) claim against Defendant Bailey, Plaintiff must first plead an actionable claim under Section 10(b) of the Exchange Act and Rule 10b-5.

complaint to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). If a plaintiff's allegation regarding the statement or omission "is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." Id. (quoting 15 U.S.C. § 78u–4(b)(1)).

Finally, the PSLRA provides "safe harbor" provisions that "sharply limit liability of companies and their management for certain 'forward-looking statements,' . . . when such statements are accompanied by appropriate cautionary language." In re Smith & Wesson Holding Corp. Sec. Litig., 669 F.3d 68, 71 n.3 (1st Cir. 2012); see 15 U.S.C. § 78u-5.[5] "[T]he definition of a forward looking statement includes 'a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer.'" Meyer v. Biopure Corp., 221 F. Supp. 2d 195, 203 (D. Mass. 2002) (quoting 15 U.S.C. § 78u-5(i)(1)(B)); see Carvelli v. Ocwen Fin. Corp., 934 F.3d 1307, 1324 (11th Cir. 2019) ("A forward-looking statement is what it sounds like—a prediction, projection, or plan."). "On any motion to dismiss based upon subsection (c)(1), the court shall consider any statement cited in the complaint and any cautionary statement accompanying the forward-

[5] The safe harbor provides that

> in any private action arising under this title that is based on an untrue statement of a material fact . . . , a person . . . shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that . . . the forward-looking statement is . . . identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement . . . .

15 U.S.C. § 78u-5(c)(1)(A)(i).

looking statement, which are not subject to material dispute, cited by the defendant." 15 U.S.C. § 78u-5(e).

III. DISCUSSION

Defendants argue that the amended complaint fails to state an actionable claim for securities fraud because (1) it fails to sufficiently allege that Defendants' statements about the timing of topline results were false when made; (2) the PSLRA safe harbor protects the topline result estimates; and (3) the allegations regarding OS results do not state a claim. [ECF No. 52 at 14, 16, 20].[6] In addition, Defendants state that Plaintiff has failed to adequately plead allegations of scienter or loss causation. [Id. at 27, 31]. Plaintiff counters that the safe harbor does not protect Defendants' statements about the timing of topline results and that the allegations about OS results demonstrate that Defendants' statements were misleading. [ECF No. 56 at 18, 24].

A. Timing Estimates and PSLRA Safe Harbor

Plaintiff claims that the safe harbor does not protect Defendants' statements concerning the timing of topline results because the statements were not forward-looking and did not contain meaningful cautionary language. [ECF No. 56 at 24–26].

As the First Circuit has acknowledged, the PSLRA

> seems to provide a surprising rule that the maker of knowingly false and wilfully [sic] fraudulent forward-looking statements, designed to deceive investors, escapes liability for the fraud if the statement is 'identified as a forward-looking statement and [was] accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'

Brody v. Stone & Webster, Inc. (In re Stone & Webster, Inc., Sec. Litig.), 414 F.3d 187, 212 (1st Cir. 2005) (alteration in original) (quoting 15 U.S.C. § 78u-5(c)(1)(A)(i)). "In other words, 'if a

[6] Defendants raised additional challenges that are no longer relevant in light of the allegations now waived by Plaintiff. See [ECF No. 56 at 14 n.3].

statement is accompanied by meaningful cautionary language, the defendants' state of mind is irrelevant.'" In re Ibis Tech. Sec. Litig., 422 F. Supp. 2d 294, 310 (D. Mass. 2005) (quoting Harris v. Ivax Corp., 182 F.3d 799, 803 (11th Cir. 1999)); see Archdiocese of Milwaukee Supporting Fund v. Inv'rs Fin. Servs. Corp., No. 05-cv-11627, 2009 U.S. Dist. LEXIS 143258, at *19 (D. Mass. Jan. 13, 2009) ("Therefore, even assuming, as the Plaintiffs assert, the Defendants knew their statements were false, such knowledge would not defeat safe harbor protection.").[7]

"The use of the words 'meaningful' and 'important factors' are intended to provide a standard for the types of cautionary statements upon which a court may, where appropriate, decide a motion to dismiss, without examining the state of mind of the defendant." In re Cytyc Corp. Sec. Litig., No. 02-cv-12399, 2005 U.S. Dist. LEXIS 6166, at *78 n.54 (D. Mass. Mar. 1, 2005) (quoting H.R. Conf. Rep. No. 104-369, *44 (1995)). Cautionary language may not simply be boilerplate, but "must be sufficiently related in subject matter and strong in tone to counter the statement made." In re Bos. Tech. Sec. Litig., 8 F. Supp. 2d 43, 53 (D. Mass. 1998).

As an initial matter, despite Plaintiff's claims to the contrary, Defendants' statements about the projected timeline for receiving and analyzing topline results were clearly forward-looking. A forward-looking statement is "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer . . . ." 15 U.S.C. § 78u-5(i)(1)(B). Statements about a projected, or planned, timeline for future results fits this definition. See Harrington v. Tetraphase Pharm., Inc., No. 16-cv-10133, 2017 U.S. Dist. LEXIS 71274, at *34 (D. Mass. May 9, 2017) (finding statements about planned

[7] Plaintiff incorrectly cites to a case alleging common law fraud to argue that the PSLRA safe harbor does not apply to statements that may have been knowingly false at the time they were made. [ECF No. 56 at 25 (citing Goldthwaite v. Sensear, Inc., No. 15-cv-13143, 2016 WL 5329635, at *3–4 (D. Mass. Aug. 25, 2016))].

NDA submission to be forward-looking). In addition to the use of language such as "expect" and "anticipate," which signals looking forward, the Company was in the midst of a clinical trial with endpoints that were by their very nature unknown and unpredictable: whether subjects would respond to an experimental treatment (measured as PFS) or die (measured as OS).

The 2017 press releases Plaintiff cites included cautionary language, warning that "forward-looking statements of AVEO . . . involve substantial risks and uncertainties" including those about "the timing of the completion of enrollment and the data readout for the TIVO-3 trial . . . ." [ECF No. 53-3 at 4]; see also [ECF No. 53-4 at 4 (identifying "the expected timelines for . . . receiving top-line data readouts in TIVO-3" as forward-looking statements that were uncertain); ECF No. 53-5 at 3 (identifying "the anticipated readout of TIVO-3 in the first quarter of 2018" as forward-looking and uncertain); ECF No. 53-6 at 3 (citing "expected timeline for reporting data from TIVO-3" as forward-looking and uncertain); ECF No. 53-7 at 4 (identifying as an uncertain forward-looking statement "the expected timeline for reporting data from TIVO-3")]. Further, the press releases stated that "[a]s a result" of the uncertainties involved in forward-looking statements, "readers are cautioned not to place undue reliance on these expectations and estimates. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors . . . ." [ECF No. 53-3 at 4]. Finally, the cautionary language also directed readers to the Company's SEC filings, which included even more extensive cautionary language about forward-looking statements. See, e.g., [id. at 4–5].

Press releases from 2018 contained similar cautionary language regarding the risks and uncertainties of forward-looking statements, including statements about the timing of topline results from TIVO-3, and directed readers to the Company's SEC filings. [ECF No. 53-10 at 3

("the expected timeline for . . . reporting data from TIVO-3"); ECF No. 53-11 at 5–6 ("the expected timeline for reporting data from TIVO-3"); ECF No. 53-12 at 3 ("the expected timeline for . . . reporting data from TIVO-3 clinical trial"); ECF No. 53-13 at 5 ("the expected timeline for reporting data from TIVO-3"); ECF No. 53-14 at 3 ("expectations regarding the timing for top line results from the Phase 3 TIVO-3 study"); ECF No. 53-15 at 4 ("expectations regarding the timing for top line results from the Phase 3 TIVO-3 study")].

Finally, the SEC filings Plaintiff cites as containing misleading statements also contained cautionary language. For example, AVEO's 10-Q filing for the first quarter of 2017 provided cautionary language to the effect that the Company was "substantially dependent on the success of tivozanib" and that "significant delays" in approval could "substantially harm" the Company. [ECF No. 53-16 at 55; Am. Compl. ¶ 137]. In addition, the Company warned that clinical trial results were beyond its control and that testing "is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all." [ECF No. 53-16 at 55–56; Am. Compl. ¶ 137].[8] Quarterly reports filed in August and November of 2017 contained the same "expect[ed]" timeline for topline data and the same

[8] The filing went on to warn:

> We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or any collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

[ECF No. 53-16 at 58]. This language was also included in the Company's 10-Q filings for the second and third quarters of 2017 and its 2017 10-K, [ECF No. 53-17 at 59; ECF No 53-18 at 57; ECF No. 53-19 at 45–46], as well as its 10-Q filings for the first and second quarters of 2018, [ECF No. 53-20 at 68; ECF No. 53-21 at 67].

cautionary language as the 10-Q for the first quarter. [ECF No. 53-17 at 30 (timeline estimate); id. at 54, 56 (cautionary language specific to clinical trial outcome and timelines); ECF No. 53-18 at 30 (timeline estimate); id. at 54, 55 (cautionary language specific to clinical trial outcome and timelines); Am. Compl. ¶¶ 145–46, 154–55]. AVEO's 2017 10-K and quarterly filings for 2018 also contained the same cautionary language as filings from 2017, including language about the possibility that clinical trial outcomes and timelines could vary. See [ECF No. 53-19 at 42; ECF No. 53-20 at 65; ECF No. 53-21 at 63–64].

Far from being boilerplate as Plaintiff claims, the cautionary language used in AVEO's press releases and SEC filings fits squarely within the safe harbor, as it explicitly identified the expected timeline of topline results as uncertain. See Leavitt v. Alnylam Pharm., Inc., No. 18-cv-12433, 2020 U.S. Dist. LEXIS 49638, at *20 (D. Mass. Mar. 23, 2020) ("[Defendant] warned investors about specific risks including deficient clinical trial results and the prospect of the FDA declining to approve the drug. Such warnings are not mere boilerplate and were sufficient to invoke the safe harbor and as such are non-actionable."). It is difficult to determine how Defendants could have more explicitly warned the public about the uncertainty of its timing estimates or what language would have satisfied Plaintiff. In any case, the language used by Defendants easily satisfies the requirements of the safe harbor. See In re Smith & Wesson Holding Corp. Sec. Litig., 604 F. Supp. 2d 332, 341 (D. Mass. 2009) (finding forward-looking statements that were "extensive and cover[ed] the ground identified by [p]laintiffs as relevant" fell within the PLSRA safe harbor).

As to statements made during conferences, "[t]he safe harbor provision also extends to oral statements in a less exacting manner. It allows a company to rely on this safe harbor when making an oral statement by simply referring to the written document containing the cautionary

language." In re Cytyc, 2005 U.S. Dist. LEXIS 6166, at *80 (citing 15 U.S.C. § 78u-5(c)(2)). When Defendant Bailey spoke at an April 2018 conference and made a statement that Plaintiff cites as misleading as to the timing of topline results, he referred attendees to cautionary language contained in AVEO's SEC filings. [ECF No. 53-2 at 2 (transcript of April 2018 conference at which Bailey advised the audience, "I'm going to make some forward-looking statements. So I refer you to our SEC documents.")]. This was sufficient to bring his statements within the safe harbor. See In re Cytyc, 2005 U.S. Dist. LEXIS 6166, at *80.

The Court finds that the challenged materials "contained forward-looking statements, as so stated therein," as well as relevant and meaningful cautionary language, "and therefore come[] under the protection of the statutory safe harbor." Baron v. Smith, 380 F.3d 49, 54 (1st Cir. 2004) (affirming dismissal where challenged press release contained cautionary language).[9]

B. November 5, 2018 Statements Regarding OS Results

Defendants argue that they did not have a duty to disclose that subjects were lost to follow-up, but state that they nevertheless did in fact disclose this information. [ECF No. 52 at 22]. Plaintiff contends that Defendants had an obligation to share complete data with investors, including to specify the number of subjects who were lost to follow-up as opposed to those who had simply withdrawn from the study, because the number of patients lost to follow-up had the potential to make the TIVO-3 OS data worse. [ECF No. 56 at 18, 19 n.5].

[9] Even if the PSLRA safe harbor did not apply, Plaintiff would have faced an uphill battle in attempting to frame timelines that were consistently described as "expected" or "anticipated" as fraudulent. See Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 457 (1st Cir. 2017) ("[T]o support a claim that [defendant's] statements were false or misleading, [plaintiff] is left only with the inference that because, in retrospect, the test lagged significantly behind the proposed timeline, the timeline must have always been impossible to achieve."); Harrington, 2017 U.S. Dist. LEXIS 71274, at *14 ("The Court will not hold that a company stating that they anticipate results 'mid-year' means that if results do not come out at the exact midpoint of the year the company has made a fraudulent statement.").

"[I]n order to prevail on a Rule 10b-5 claim, a plaintiff must show that the statements were misleading as to a material fact. It is not enough that a statement is false or incomplete, if the misrepresented fact is otherwise insignificant." Basic Inc. v. Levinson, 485 U.S. 224, 238 (1988). In addition, "[w]hile a company that chooses to reveal material information, even though it had no duty to do so, 'must disclose the whole truth,' it need not disclose everything it knows . . . ." In re SeaChange Int'l, Inc., No. 02-cv-12116, 2004 U.S. Dist. LEXIS 1687, at *26 (D. Mass. Feb. 6, 2004) (quoting Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987)). When "[t]he further disclosure of these negative outcomes and unknowns would not have 'significantly alter[ed] the total mix of information available to shareholders' . . . . The omissions are . . . not material." Whitehead v. Inotek Pharm. Corp., No. 17-cv-10025, 2018 U.S. Dist. LEXIS 173728, at *18 (D. Mass. June 27, 2018) (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 38 (2011)). Although "[t]he falsity of a statement and the materiality of a false statement are questions for the jury," a court is nonetheless "free to find, as a matter of law, that a statement was not false, or not materially false, only if a jury could not reasonably find falsity or materiality on the evidence presented." Brody, 414 F.3d at 209 (internal citations omitted).

In its November 5, 2018 press release, AVEO made clear that its OS results were incomplete as only 46% of OS events had been reported at that time. [ECF No. 53-23 at 2 (informing investors that "analysis of the secondary endpoint of overall survival (OS) was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported")]. The Company also informed investors that more complete OS data would not be available until August 2019, nearly one year later. [Id.]. Defendant Needle reiterated this point during the investor call that same day, warning that "overall survival was not mature at the time

of the final PFS analysis, with only 46% of potential OS events having been reported, representing 161 patients." [ECF No. 53-1 at 6]. As a result,

> 149 patients remained in active follow-up, another 41 patients withdrew consent or were lost to follow-up. . . . Efforts are underway to determine the survival status of as many of these patients as possible. . . . [A] little over 40 patients remain on study therapy . . . . [therefore t]hese patients will continue to affect the OS analysis. . . . [W]e cannot currently make any predictions about what the final OS analysis for TIVO-3 will show . . . .

[Id.].[10]

The Company disclosed that the results were not yet complete and indicated that it was actively attempting to gather additional data on "as many of these patients as possible"—putting investors on notice that subjects who had withdrawn or been lost to follow-up might still contribute data to the study along with the still active subjects. See [ECF No. 53-1 at 6]. Plaintiff has failed to demonstrate that knowing the exact number of additional results that might be provided through previously-lost-to-follow-up subjects versus withdrawn subjects or active subjects would be relevant in the "total mix" of information provided to investors. The Company emphasized that, regardless of the source of those additional OS results, the results could change the outlook of tivozanib for better or worse. See [id. ("[W]e cannot currently make any predictions about what the final OS analysis for TIVO-3 will show . . . .")].

Plaintiff cites to a January 31, 2019 press release which indicated that additional OS results from lost to follow-up subjects had a negative impact on study results, but which also stated that the study was ongoing and that the Company would continue to collect OS data throughout 2019. [ECF No. 53-22 at 2; ECF No. 56 at 14–15]. In response to a recommendation

[10] The Court notes that cautionary language in AVEO's SEC filings addressed the potential for subjects who might be lost to follow-up: "patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, . . . or extend the clinical trial's duration . . . ." [ECF No. 53-16 at 57].

from the FDA as to these new OS results, AVEO further announced its intention to delay filing an NDA for tivozanib until additional OS results were available. [ECF NO. 53-22 at 2]. Having found out in January 2019 that OS results from lost to follow-up subjects were impactful in the short term, however, does not support Plaintiff's allegations that the number of subjects lost to follow-up would have been material in November 2018 as those results—just like results from withdrawn or active subjects—could have just as easily have had a positive impact on the study. The First Circuit has emphasized that "[a] plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." Advest, 512 F.3d at 62 (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1223 (1st Cir. 1996)). Further, the Company warned investors that additional OS data—regardless of the source—could have an unpredictable effect on the study. [ECF No. 53-1 at 6 ("[W]e cannot currently make any predictions about what the final OS analysis for TIVO-3 will show . . . .")].

Because "[t]he further disclosure of these . . . unknowns would not have 'significantly alter[ed] the total mix of information available to shareholders' . . . . The omissions are therefore not material." Whitehead, 2018 U.S. Dist. LEXIS 173728, at *18. The Court finds that "a jury could not reasonably find falsity or materiality on the evidence presented." Brody, 414 F.3d at 209.[11] Having failed to plead an essential element of his claim, Plaintiff fails to state a claim for violations of Section 10(b) and Rule 10b-5.

[11] As a final point, Plaintiff also fails to support the second element, scienter, of his Section 10(b) and Rule 10b-5 claim. Complaints that adequately allege scienter "often contain[] clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012). Plaintiff argues that, despite the fact that his amended complaint contains no such allegations, his general allegations that the Company was in financial straits and dependent on the success of TIVO-3 is sufficient. [ECF No. 56 at 22

IV. CONCLUSION

Defendants' statements regarding the timing of topline results in the TIVO-3 clinical trial are protected by the PSLRA safe harbor. Further, Plaintiff has failed to allege a material misrepresentation or omission sufficient to state a claim under Section 10(b) and Rule 10b-5. Accordingly, Defendants' motion to dismiss, [ECF No. 51], is GRANTED.[12]

SO ORDERED.

July 24, 2020

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

(citing Kader, 887 F.3d at 60) (suggesting that allegations that the Company's success was "on the line" could be sufficient to allege scienter)]. In Kader, the First Circuit cited to Bielski v. Cabletron Systems for the proposition that scienter may be found where there are allegations that "executives' careers and the very survival of the company were on the line." 311 F.3d 11, 39 (1st Cir. 2002). In Bielski, however, the company had not publicly disclosed its financial straits—whereas here, AVEO was candid in its SEC filings about the fact that the Company was "substantially dependent on the success of tivozanib" and that "significant delays" in approval could "substantially harm" the Company. [ECF No. 53-16 at 55]. Similar warnings were contained in the cautionary language included in the Company's press releases. See, e.g., [ECF No. 53-23 at 4 ("AVEO faces other risks relating to its business as well, including risks relating to its ability to file an NDA for tivozanib in the time frame it currently estimates; its and its collaborators' ability to successfully enroll and complete clinical trials, including the TIVO-3 . . . studies")]. In addition, the First Circuit in Bielski pointed to a number of factors that supported scienter and did not rely solely on the allegations regarding the company's secret financial peril. See 311 F.3d at 39.

[12] Because Plaintiff fails to plead a viable claim for securities fraud under Section 10(b) and Rule 10b-5, his derivative claim against Defendant Bailey under Section 20(a) necessarily fails as well. See Hill, 638 F.3d at 70.